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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/090,798	03/06/2002	Amanda S. Schilling	83202	6616

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EXAMINER	
SRIVASTAVA, KAILASH C	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 03/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/090,798	SCHILLING ET AL.	
	Examiner	Art Unit	
	Dr. Kailash C. Srivastava	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19 and 21* is/are pending in the application.

4a) Of the above claim(s) *17-19 and 21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' amendment and response filed November 19, 2003 to Office Action mailed September 9, 2003 is acknowledged and entered. The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office action.

2. Claim 20 has been cancelled.

3. Claims 1-19 and 21 are pending.

4. Claim 2 has been amended.

5. Claims 17-19 and 21 have been previously withdrawn. Examiner suggests that to expedite prosecution, said non-elected, previously withdrawn claims be canceled in response to this Office action.

6. Claims 1-16 are examined on merits.

Claim Rejections – 35 U.S.C. § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> ***A person shall be entitled to a patent unless –***
>
> ***(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.***

8. Claims 1-3, 9-10 and 16 are rejected under 35 U.S.C. §102(e) as anticipated by Baugh et al. (U.S. Patent 6,656,919).

Claims recite a method to simultaneously or sequentially germinate and kill biological spores via treating said spores with a germinant comprising water, dipicolinic acid and calcium as calcium chloride and a germicidal solution that comprises a peroxygen compound.

Baugh et al. teach a method to disinfect or sterilize surfaces or materials contaminated with one or more members selected from bacteria or bacterial spores, wherein *Bacillus cereus* or *Bacillus anthracis* spores are rendered harmless or lifeless or sterilized by subjecting said spores simultaneously to a germinant and a germicidal solution. Alternatively, said spores are first treated with said germinant solution and subsequently with said germicidal solution. This one or two-step process kills said bacterial spores (Column 5, Lines 14-24, 30-35 and 48-58) and sterilizes the surface contaminated with bacterial spores. Said germinant solution comprises one among: adenine, L-alanine, calcium, dipicolinate, glucose and various organic or inorganic anions, and cations in distilled water. Baugh et al. further teach that

upon contact with a germinant that does not initially contain dipicolinic acid, with induction of germination, dipicolinic acid is released from the spores into the germinant solution and acts as a germinant for remaining un-germinated spores (Column 7, Lines 30-33). Thus, inherently also Baugh et al's germinant solution comprises dipicolinic acid, calcium as calcium chloride and water concentration in range of 50 to 98 weight percent. Additionally, said germicidal solution comprises art-known bactericidal compound/ compounds or mixtures of such compounds with surfactants and peroxide compounds (e.g., benzoyl and hydrogen peroxides, see Baugh et al., Column 8, Line 26 to Column 12, Line 55). In microbiological art, bacterial spores are recognized as biological spores. Thus, Baugh et al. teach a method to sterilize materials or surfaces contaminated with biological spores comprising same steps and components as are recited in the instantly claimed invention.

Therefore, the reference deems to anticipate the cited claims.

Claim Rejections Under 35 U.S.C. § 103(a)

9. Claims 1-16 are rejected under 35 U.S.C. § 103 (a) as obvious over Baugh et al. (U.S. Patent 6,656,919) in view of Paidhungat et al. (Journal of Bacteriology.2000, Volume 182, Pages 2513-2519) and Baker et al (U. S. Patent 6,506, 803).

Claims recite a method to simultaneously or sequentially germinate and kill biological spores via treating said spores with a germinant comprising dipicolinic acid and calcium and a germicidal solution, wherein the germinant solution comprises 50-90 mM of each one of calcium ions and dipicolinic acid. The compositions administered in said method also comprise a germicidal solution, a surfactant comprising at least one carbon chain of at least ≥ six carbon members, a peroxide compound and an enzyme.

Teachings from Baugh et al. have already been discussed *supra.* Baugh et al., in their method of simultaneously germinating and sterilizing *Bacillus* spores further teach that said germicidal composition comprises non-ionic, anionic and cationic surfactants, wherein said non-ionic surfactants are comprised of compounds having carbon chain in range of 8 to 18 carbon atoms (Column 11, Lines 12-64). Since Baugh et al. teach a method, wherein biological spores are simultaneously germinated and killed (Column 13, Lines 31-44) via mixing together a bacterial spore suspension, a germinant solution and a germicidal solution; intrinsically Baugh et al. teach a method to disinfect or sterilize a surface or material via germinating and killing biological spores with a composition comprising water, dipicolinic acid, calcium ions (from the germinant solution), anionic, cationic or nonionic surfactant, wherein the carbon chain length of said surfactant compound ranges between 8-18 and a peroxide (e.g., benzoyl or hydrogen peroxide). Please note that carbon chain length in range of 8-18 encompasses carbon chain length of >6 carbon chain length. Furthermore, Baugh et al. also illustrate a method, wherein the same composition is

sprayed on a contaminated surface (i.e., agar surface contaminated with bacterial spores) to decontaminate and sterilize said surface (Column 13, Example 6).

Baugh et al., however, do not teach concentrations of dipicolinic acid and calcium, nor an enzyme in their composition.

Paidhungat et al. teach a method to germinate *Bacillus* spores, wherein *Bacillus* spores are added to a germinant comprising a calcium (i.e., Ca^{2+})- dipicolinic acid (i.e., DPA) concentration in range of <20 mM to 90 mM with highest germination when the concentration of each component, i.e. Ca^{2+} and DPA each in the germinant was equimolar at 60 mM (Page 2517, Column 2, Lines 17-29 under Table 4 and Figure 4).

Baker et al. teach a method and a composition to inactivate/ decontaminate bacterial cells and spores by exposing them to an oil-in-water emulsion comprising water, a surfactant, oil, an enzyme and a buffer (Abstract, Lines 1-7; Column 5, Lines 12-15; Column 12, Lines 7-64; Column 18, Lines 18-20; Column 21, Lines 1-32; Column 22, Lines 27-40).

Thus, an artisan of ordinary skill, at the time that said invention was made would be motivated to combine the teachings from each one of the cited references to develop a method to decontaminate or sterilize a material or a surface by either simultaneous or sequential application of a germinant solution and a germicidal solution, because Baugh et al. reference teaches the general principle of germinating and killing biological spores and Baugh et al. further teach either simultaneous or sequential killing of said germinated biological spores, wherein said germinant solution comprises dipicolinic acid and calcium ions and said germicidal solution comprising a peroxide solution and an anionic, cationic or nonionic surfactant with carbon chain length of said surfactant ranges between 8-18; Paidhungat et al. teach that concentration of each of dipicolinic acid and calcium ions in said germinant solution ranges between 20 to 90 mM and the optimal concentration of each of dipicolinic acid and calcium ions in said germinant solution is 60 mM, and Baker et al. teach a method and a composition to inactivate bacterial/fungal spores (i.e., biological spores), wherein said composition comprises water, surfactant and an enzyme. Thus, Paidhungat et al. remedy the deficiency of concentration of each of dipicolinic acid and calcium ions in the teachings from Baugh et al. and Baker et al. remedy the deficiency of an enzyme and a surfactant in the germinant composition from Baugh et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method and composition of Baugh et al., according to the teachings from Paidhungat et al. and Baker et al., because Baugh et al. teach the general principle of first germinating the biological

spore, wherein biological spores are simultaneously/sequentially germinated and killed. Paidhungat et al. remedy the deficiency of optimal concentration (i.e., 60 mM for each component) of dipicolinic acid and calcium ions in Baugh et al's composition and method, and Baker et al. remedy the deficiency of enzyme and surfactant in the disinfectant composition of Baugh et al.

None of the above discussed prior art references teach the exact same concentration for water, dipicolinic acid or surfactant on weight basis of the total composition. However, the adjustment of particular conventional working conditions (e.g., the ratios of each one of components in a composition, or their molar concentration etc.) is deemed merely a matter of judicious selection and routine optimization of a result-effective parameter which is well within the purview of the skilled artisan.

From the teachings of the references cited *supra*, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

10. Claims 1-16 are rejected under 35 U.S.C. § 103 (a) as obvious over Clouston (U.S. Patent 3,617,178) in view of Paidhungat et al. (Journal of Bacteriology.2000, Volume 182, Pages 2513-2519) and Baker et al (U. S. Patent 6,506, 803).

The claimed invention has been summarized *supra.*

Clouston teaches a method to simultaneously germinate *Bacillus*/Clostridial spores present in a liquid or a solid material and sterilize said material. Alternatively, said material is disinfected by a method, wherein bacterial spores are first germinated and in a subsequent step germinated spores are killed by heat, chemical or radiation treatment. In said simultaneous/ sequential method of germination and sterilization, the spores are germinated via treating the contaminated material with a hydrostatic pressure in range of 100 psi to 20,000psi accompanied with simultaneous or subsequent heat (up to 80° C) gamma or UV radiation (Column 1, Line 34 to Column 2, Line 19). Said germination is enhanced with addition of an exogenous anion or cation compound (Column 1, Lines 16-19). Thus, intrinsically, Clouston teaches the general principle of first or simultaneous germinating and killing of bacterial spores to sterilize/decontaminate a liquid/solid contaminated with bacterial spores.

Clouston, while teaching enhancement of germination in presence of cation solutes, does not teach dipicolinic acid and calcium, nor a surfactant or an enzyme in the germinant composition. Paidhungat et al's method comprising a germinant containing <20 mM to 90 mM calcium ions and

dipicolinic acid to germinate *Bacilllus* spores as well as Baker et al's method and composition to germinate and inactivate bacterial cells and spores by exposing them to an oil-in-water emulsion comprising water, a surfactant, oil, an enzyme and a buffer (Abstract, Lines 1-7; Column 5, Lines 12-15; Column 12, Lines 7-64; Column 18, Lines 18-20; Column 21, Lines 1-32; Column 22, Lines 27-40) has been detailed *supra.*

Thus, an artisan of ordinary skill, at the time that said invention was made would be motivated to combine the teachings from each one of the cited references to develop a method to decontaminate or sterilize a material contaminated with biological/bacterial spores by either simultaneous or sequential application of a germinant and a germicidal material, because Clouston and Baker et al. teach the general principle of germinating and killing biological spores, Clouston further teaches either simultaneous or sequential killing of said germinated biological spores; Paidhungat et al. teach that a germinant solution to germinate *Bacillus* spores comprises each of dipicolinic acid and calcium ions in said germinant at a concentration range between 20 to 90 mM and the optimal concentration of each of dipicolinic acid and calcium ions in said germinant is 60 mM, and Baker et al. teach that said germinant solution is comprised of water, surfactant and an enzyme. Thus, Paidhungat et al. remedy the deficiency of concentration of each of dipicolinic acid and calcium ions in Clouston's teachings and Baker et al. remedy the deficiency of an enzyme and a surfactant in germinant composition in Clouston's teachings.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modify Clouston's method and composition according to the teachings from Paidhungat et al. and Baker et al., because Clouston teaches the general principle of first germinating the biological spore and subsequently kill the germinated spores through subjecting said germinated spores to heat, chemical or radiation or alternatively, simultaneously subjecting materials contaminated with biological spores to a pH solution, pressure and heat/radiation or chemical. Paidhungat et al. remedy the deficiency of dipicolinic acid and calcium ions in Clouston's teachings, and Baker et al. remedy the deficiency of enzyme and surfactant in Clouston's method.

None of the above discussed prior art references teach the exact same concentration for water, dipicolinic acid or surfactant on weight basis of the total composition. However, the adjustment of particular conventional working conditions (e.g., the ratios of each one of components in a composition, or their molar concentration etc.) is deemed merely a matter of judicious selection and routine optimization of a result-effective parameter, which is well within the purview of the skilled artisan.

From the teachings of the references cited *supra*, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the

invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

11. In response to the rejections under 35 U.S.C. § 103 (a) in the Office Action mailed September 9, 2003, applicants argue that, "the individual or combined teachings from cited references do not make the claimed invention obvious because examiner has erroneously characterized the order of germinating and sterilizing of biological spores in a material or a surface contaminated with biological spores as well as the teachings from the references cited in said Office Action.

Applicants' arguments regarding the rejections to Claims 1-16 under 35 U.S.C.§103(a) in Office Action mailed September 9, 2003 have been fully considered carefully and examiner has reexamined the claimed invention in the order (i.e. either simultaneous or sequential germinating and killing of biological spores to sterilize/decontaminate a material or a surface) that the applicants have claimed the germination and killing of biological spores as discussed *supra*.

In response to applicants' arguments against the references individually, one cannot show non-obviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In response to applicants' argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir.1992). In the instant case, those reasons are cited at items 10-11 *supra*. Furthermore, a rejection under 35 U.S.C. § 103 (a) based upon the combination of references is not deficient solely because the references are combined based upon a reason or technical consideration which is different from that which resulted in the claimed invention (*Ex parte Raychem Corp*, 17 U.S.P.Q. 2d 1417).

CONCLUSION

12. No Claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743 Monday through Thursday. The fax phone number for the organization where this application or proceeding is assigned is (703)-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Kailash C. Srivastava, Ph.D.
Patent Examiner
Art Unit 1651
(571) 272-0923

March 2, 2004

FRANCISCO PRATS
PRIMARY EXAMINER